



PATENT APPLICATION IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Karl-Hermann, SCHLINGENSIEPEN et al.

Application No: 10/591,048 Examiner: To Be Assigned

35 U.S.C. §371 (c) date: March 28, 2007 Group Art Unit: 1641

Attorney Docket No: 4052-003 Confirmation No. 4668

Customer No: 30448

For: PHARMACEUTICAL COMPOSITION

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97(b) and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56, the references cited on the accompanying forms PTO/SB/08A and PTO/SB/08B are hereby brought to the attention of the Examiner for independent evaluation. In accordance with the Rules in effect for applications filed after June 30, 2003, copies of U.S. patents and/or patent application publications are not enclosed. Copies of all foreign patents and non-patent references are enclosed herewith. Some of the references were cited in the International Search Report, which is enclosed, and some were noted in the specification of the present patent application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the listed documents be considered by the Examiner and made part of the record in the present application and that an initialed copy of forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

In re Application of Karl-Hermann SCHLINGENSIEPEN, et al Application No. 10/591,048 Page 2 of 2

Certification

This Statement is being filed before the receipt of the first Office Action on the merits, a fee is not required for consideration of these documents. Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged to Deposit Account No. 50-0951.

Respectfully submitted,

Date: May 17, 2007

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PTO/SB/08A (09-06)

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ibstitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number 10/591,048				
Filing Date 371 rcvd PTO Aug. 28, 2006				
First Named Inventor Karl-Hermann SCHLINGENSIEPE				
Art Unit	1641			
Examiner Name To Be Assigned				
Attorney Docket Number	4052-003			

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ^{2 (# known)}	40/47/4074	7-4:	- Igares ippear
	1	^{US-} 3,854,480	12/17/1974	Zaffaroni	<u> </u>
	2	^{US-} 4,452,775	06/05/1984	Kent	
	3	^{US-} 4,469,863	09/04/1984	Ts'o, et al	
	4	^{US-} 4,675,189	06/23/1987	Kent, et ai	
	5	^{US-} 5,023,243	06/11/1991	Tullis	
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·	7	^{US-} 5,133,974	07/28/1992	Paradissis, et al	
	8	^{US-} 5,407,686	04/18/1995	Patel, et al	
	9	^{US-} 5,539,082	07/23/1996	Nielsen, et al	
	10	^{US-} 5,714,331	02/03/1998	Buchardt, et al	
	11	^{US-} 5,719,262	02/17/1998	Buchardt, et al	
	12	^{US-} 5,736,152	04/07/1998	Dunn	
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	-	FOREIGN	PATENT DOCU	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	⊤ 6
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	1
	1	WO 99/63975 A	12/19/1999	Biognostik Gesellschaft Fuer		
	2	WO 94/25588 A	11/10/1994	Biognostik Gesellschaft Fuer		
	3	EP 1008649 A2	06/14/2000	Biognostik Gesellschaft Fuer		
	4	EP 0695354	01/09/2002	Biognostik Gesellschaft Fuer		
	5	EP 0092574 (WO 83/01451)	04/28/1983	Molecular Biosystems, Inc.		

Examiner	Date	["-
Signature	Considered	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO	Complete if Known		
Casalida (a. 1611) 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Application Number	10/591,048	
INFORMATION DISCLOSURE	Filing Date	371 rcvd PTO Aug. 28, 2006	
STATEMENT BY APPLICANT	First Named Inventor Karl-Hermann SCHLINGENSIEP		
(Use as many sheets as necessary)	Art Unit	1641	
(Use as many sheets as necessary)	Examiner Name To Be Assigned		
Sheet 2 of 4	Attorney Docket Number	4052-003	

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*			T ²	
	1	SPEARMEN, M, et al; "Antisense Oligodeoxyribonuleotide Inhibition of TGF-betal Gene Expression and Alterations in the Growth and Malignant Properties of Mouse Fibrosarcoma Cells"; Gene, Elsevier Biomedical Press, Amsterdam, NL; Vol. 149,; 1994; pp: 25-29		
	2	HUANG, FEI, et al; "Transforming Growth Gactor Brta-1 (TGF-beta-1) is an Autocrine Positive Regulator of Colon Carcinoma U9 Cells in Vivo as Shown by Transfection of a TGF-beta-1 Antisense Expression Plasmid"; Cell Growth and Differentiation; Vol. 6; No. 12; Dec. 1995; pp: 1635-1642		
	3	JACHIMCAZK, P., et al; "Transforming Growth Factor-Beta-Mediated Autocrine Growth Regulation of Gliomas as Detected with Phosphorothioate Antisense with Oligonucleotides"; International journal of Cancer, NY, NY, Vol. 65; No. 3; 26 Jan. 1996; pp: 332-337		
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	5	LEE, et al; "Mucosal Penetration Enhancers For Facilitation of Peptide and Protien Drug Absorption"; Critical Reviews in Therapeutic Drug Carrier Systems; Vol. 8; 1991; pp: 91-192		
	6	MURANISHI; "Absorption Enhancers"; Critical Reviews in Therapeutic Drug Carrier Systems; Vol. 7; 1990; pp: 1-33		
	7	WAGNER, et al; "Potent and Selective Inhibition of Gene Expression by an Antisense Heptanucleotide"; Nature Biotechnology; Vol. 14; July 1996; pp: 840-844		
	8	WENGEL, J., et al; "LNA (Locked Nucleic Acid)"; Nucleoslides & Nucleotides; Vol. 18 (6 & 7); 1999; pp: 1365-1370		
· · · · · ·	9	HARDMAN, et al, eds.; Section VI Drugs Affecting Gastrointestinal Function; McGraw-Hill; NY, NY; 1996; pp: 934-935		
	10	WIKSTROM, P. et al.; Transforming Growth Factor-b1 and Prostate Cancer; Scand J. Urol Nephrol 34, Sweden		

Examiner	Date	
Signature	Considered	

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perwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/591,048 Filing Date INFORMATION DISCLOSURE 371 rcvd PTO Aug. 28, 2006 STATEMENT BY APPLICANT First Named Inventor Karl-Hermann SCHLINGENSIEPEN Art Unit 1641 (Use as many sheets as necessary) **Examiner Name** To be assigned Attorney Docket Number Sheet 3 4 4052-003

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	11	GOODCHILD J.; Bioconjugate Chemistry "Conjugates of Oligonucleotides and Modified Oligonucleotides: A Review of Their Synthesis and Properties, May/June 1990, Volume 1, No.3	
	12	KOCH T.; Locked nucleic acids: a family of high affinity nucleic acid probes, Journal of Physics: Condensed Matter	
	13	LANGER, R. New Methods of Drug Delivery, September 1990	
	CHRISTENSEN, et al.; A Novel Class of Oligonucleotide Analogues Containing 2'-0,3'-Linked [3.2.0]Bicycloarabinonucleoside Monomers: Synthesis, Thermal		
		Affinity Studies, and Molecular Modeling; 1998 America Chemical Society	
	15	NIELSEN, P., et al.; Sequence-Selective Recognition of DNA by Strand Displacement with a Thymine-Substituted Polyamide	
	16	UHLMANN, E. et al.; Chemical Reviews "Antisense Oligonucleotides: A New Therapeutic Principle, Volume 90, Number 4, June 1990	
	17	FROEHLER, B., et al.; Synthesis of DNA via deosynucleoside H-phosphonate intermediates, Nucleic Acids Research, Volume 14 Number 13 1986	
	18	GAFFNEY B., et al.; Large-Scale Oligonucleotide Synthesis By The H-Phosphonate Method; Tetrahedron Letters, Vol. 29, No. 22, pp 2619-2622, 1988	
	19	GAREGG, J. et al.; Nucleoside H-Phosphonates. IV. Automated Solid Phase Synthesis Of Oligooribonucleotides By The Hydrogenphosphonate Approach; Tetrahedron Letters, Vol 27	

Examiner	Date	
Signature	Considered	

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*			T ²
	20	GAREGG J., et al.; Nucleoside H-Phosphonates. III. Chemical Synthesis of Oligodeoxyribonucleotides by the Hydrogenphosphonate Approach; Tetrahedron Letters, Vol 27, No. 34	
	21	WOJTOWICZ-PRAGA, S.; Reversal of tumor-induced immunosuppression by TGF-B inhibitors; Investigational New Drugs 21: 21-32, 2003	
	22	BEAUCAGE S.L. et al; Deoxynucleoside Phosphoramidites-A New Class of Key Intermediates for Deoxypolynucleotide Synthesis; Tetrahedron Letters, Vol. 22, No. 20	
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	24	EL-HAIRI, L., et al; The Mitigating Effects Of Phosphatidylcholines On Bile Salt-and Lysophosphatidylcholine-induced Membrane Damage; J. Pharm Pharmacol. 1992 44: 651-654	
	25	YAMASHITA, S. et al.; Effects of diclofenac sodium and disodium ethylenediaminetetraacetate on electrical parameters of mucosal membrane	
		and their relation to the permeability enhancing effects in the rat jejunum; J.Pharm, Pharmacol, 1987, 39: 621-626	

			
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